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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PARAS JR, PETER	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,644	LIU ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-105* is/are pending in the application.

4a) Of the above claim(s) *36-45 and 55-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35,46-54 and 96-105* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/5/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1002, 0903*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-105 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-35, 46-54 and 96-105, drawn to a transgenic nematode, a method of generating the same nematode, methods of expressing a polynucleotide in a C. elegans amphid sheath cell, and methods of expressing a polypeptide in a C. elegans amphid sheath cell, classified in classes 800, 800, and 800 subclasses 13, 3, and 25.

II. Claims 36-45, drawn to methods of using a nematode to identify a compound that inhibits a nematode secretion pathway, classified in class 800, subclass 3.

III. Claims 55 and 57, drawn to a pharmaceutical composition comprising an unknown compound and a method of treating or reducing the likelihood of a nematode infection in an individual using the same pharmaceutical composition, are unclassifiable as the compound is unknown.

IV. Claims 56 and 58-60, drawn to an anti-nematode agent comprising an unknown compound and methods of preventing or reducing nematode infestation of a plant using the same anti-nematode agent, are unclassifiable as the compound is unknown.

V. Claims 61-71, drawn to methods of identifying a target for anti-nematode compound development comprising identifying a mutant nematode having

a mutation in a gene and further comprising identifying the mutated gene, classified in classes 435 and 435, subclasses 6 and 440.

VI. Claim 72, drawn to a mutant nematode, classified in class 800, subclass 8.

VII. Claims 73-95, drawn to vectors, classified in class 435, subclass 320.1.

Note: Group VII, if elected, may be subject to further restriction, as the vectors, embraced by the claims of Group VII, comprise different polynucleotides encoding different polypeptides.

Inventions I, III, IV, VI and VII are distinct each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the products of Groups I, III, IV, VI and VIII are structurally distinct each having a different function from the other, wherein each can be used in materially different methods. For example the transgenic nematode of Group I can be used to produce a protein, the pharmaceutical composition of Group III can be used to treat a nematode infection in an animal, the anti-nematode agent of Group IV can be used to treat nematode infestation of a plant, the mutant nematode of Group VI is not transgenic and is therefore structurally different from the transgenic nematode of Group I and can be used in methods requiring a mutant nematode having a mutant phenotype, and the vectors of Group VII can be used

to transform somatic cells *in vitro*. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions II and V are distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are materially different methods have different modes of operation and different functions. For example the method of Group II can be used for identifying compounds that inhibit a nematode secretion pathway while the method of Group V can be used to identify a mutant nematode. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and separate search requirement, restriction for examination purposes as indicated is proper.

Inventions [I, III, IV, VI and VII] and [II, and V] are distinct each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the products of Groups I, III, IV, VI and VII can be used in materially different methods that require different technical considerations from the methods of Groups II and V. The methods of Groups II and V require different products having different structures from the products of

Groups I, III, IV, VI and VII. For example the method of Group II can be practiced using a wild-type nematode while the nematodes of Groups I and VI are transgenic and mutagenized, respectively. The method of Group V is used for identifying a mutant nematode and does not appear to require the transgenic nematode of Group I, the compounds of Groups III or IV, the mutant nematode of Group VI or the vectors of Group VII. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and separate search requirement, restriction for examination purposes as indicated is proper.

During a telephone conversation with Monica Gerber on 2/3/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-35, 46-54, and 96-105. Affirmation of this election must be made by applicant in replying to this Office action. Claims 36-45 and 55-95 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached **N**otice To Comply With Requirements For Patent Applications Containing **N**ucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. *Any* response to this Office Action, which fails to meet all of these requirements, will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Drawings

The drawings filed on 8/5/02 are approved.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35, 46-54, and 96-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a transgenic nematode whose cells comprise a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker. The claims are further directed to a method of making a nematode whose cells comprise a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker. The claims are further directed to methods of expressing a polynucleotide sequence in an amphid sheath cell of a C. elegans. Particular claim embodiments are directed to vap-1 and vap-2 regulatory elements.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v.

Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The DNA sequences of all regulatory elements of genes encoding nematode secretory products or homologs thereof encompassed within the genus of nematode regulatory elements have not been disclosed. Based upon the prior art there is expected to be sequence variation among the species of DNA sequences of nematode regulatory elements. The specification contemplates that the regulatory elements of nematode genes can be found between 1 nucleotide and 10 KB upstream of the start codon of a vap gene, for example (see page 69). The specification has also contemplated that the putative regulatory elements of *C. elegans* vap-1 and vap-2 genes may be contained within sequences 4.8 and 4.6 KB upstream from the start codon, respectively. See pages 74-77. The specification however has not disclosed the sequences of any of the regulatory elements embraced by the claims. There is no evidence on the record of a relationship between the structures of the DNA molecules of any of the embraced regulatory elements that would provide any reliable information about the structure of DNA molecules within the genus. There is no evidence on the record that embraced regulatory elements had known structural relationships to each other; the art indicated that there is variation between DNA sequences of various nematode regulatory elements. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants

effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of regulatory elements of genes encoding nematode secretory products or homologs thereof encompassed within the genus of nematode regulatory elements lack a written description. The specification fails to describe what DNA molecules fall into this genus. The skilled artisan cannot envision the detailed chemical structure of the encompassed regulatory elements, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed

by member of the genus of nematode regulatory elements. Moreover, the art has recognized that there would be variation among the species of the genus of DNA sequences of nematode regulatory elements as such regulatory elements appear to be specific for particular genes from different species of nematodes. Therefore, Applicant was not in possession of the genus of nematode regulatory elements as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 1-35, 46-54 and 96-105 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a transgenic nematode whose cells comprise a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker. The claims are further directed to a method of making a nematode whose cells comprise a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker. The claims are further directed to methods of

expressing a polynucleotide sequence in an amphid sheath cell of a *C. elegans*. Particular claim embodiments are directed to vap-1 and vap-2 regulatory elements.

The specification discusses that the invention features transgenic nematodes whose cells comprise a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker. See page 5. The specification discusses that the invention features methods of generating such nematodes, which can be used for screening of protein secretion inhibitors and/or stimulators. See page 9. However, the specification fails to provide any relevant teachings or specific guidance with regard to the nematode regulatory elements embraced by the claims. The specification also fails to provide any relevant teachings or specific guidance with regard to use and/or production of nematodes, other than *C. elegans*. Given the lack of guidance provided by the specification it would have required undue experimentation to practice the invention as claimed.

The specification has not provided relevant teachings or guidance for use of regulatory elements or nematodes other than *C. elegans* as embraced by the claims. The specification has contemplated that regulatory elements of genes encoding nematode secretory products or homologs thereof may be used in practice of the claimed invention. The specification has also contemplated that transgenic nematodes other than *C. elegans* may be created. However, the specification has failed to the other nematodes or any of the nematode regulatory elements necessary to practice the claimed methods. Moreover, the specification has failed to provide any guidance,

working examples, or relevant teachings that would allow the skilled artisan to use any nematode regulatory elements when practicing the claimed invention and the specification has not provided any correlation between use of *C. elegans* and any other nematode embraced by the claims. The specification has merely contemplated that a regulatory element may be contained within the DNA sequence between 1 nucleotide and 10KB upstream from the start codon (see page 69). Regulatory elements such as promoters have specific 5' and 3' boundaries as well as particular transcription factor binding elements.

For example, the specification has contemplated that the putative regulatory elements of *C. elegans* vap-1 and vap-2 genes may be contained within sequences 4.8 and 4.6 KB upstream from the start codon, respectively. See pages 74-77. The specification however has not provided the sequences of any of the regulatory elements embraced by the claims. As such the specification has failed to provide the guidance necessary for use of all nematode regulatory elements.

In addition, with regard to activity of nematode promoters and expression of heterologous genes across species of nematodes, the state of the art sets forth a level of unpredictability. The art suggests that promoters from particular species of nematodes do function equivalently in other species of nematodes. Boag et al (International Journal for Parasitology, 2003, 33: 313-325) observe that the mpp1 promoter from *Oesophagostomum dentatum*, a nematode from the order Strongylida, fails to direct transcription of a GFP gene in *C. elegans*. See page 323, in the last paragraph of column 2 as well as throughout the entire document. Britton et al

(Molecular and Biochemical Parasitology, 1999, 103 : 171-181) teach that promoters obtained from parasitic nematodes, such as *Ostertagia circumcincta* and *Haemonchus contortus*, when introduced in *C. elegans* result in spatial expression correlating to expression profiles in the parasite; however the timing of such expression in *C. elegans* fails to correlate to timing of expression in the parasite. See the abstract and throughout the entire document. The timing of expression of a heterologous protein in a transgenic nematode could no doubt affect any resulting phenotype. The art also suggests that expression levels of heterologous proteins may vary according to target cell and promoter used. See Lakso et al (Journal of Neurochemistry, 2003, 86: 165-172) which reports differences in the levels of human α-synuclein expression in neurons of transgenic *C. elegans*; the expression of human α-synuclein was under the control of three different neuronal promoters. Finally, the art sets forth that the function of certain nematode proteins in not conserved across species of nematodes. In particular, Winter et al (Journal of Biological Chemistry, 2003, 278(4): 2554-2562) observe that PHY-1 from *Brugia malayi* fails to rescue function in a C. elegans P4H mutant. See the abstract and throughout the entire document. As such the cited art as a whole is suggesting that transgene expression between species of nematodes can result in different and unpredictable phenotypes that are promoter and heterologous gene dependent.

As previously stated the specification has not even identified or provided the regulatory elements necessary to practice the claimed invention. A mere statement that nematode regulatory elements exist and could be used is not sufficient to enable the

breadth of the claims as directed to any nematode regulatory element. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See Genentech Inc. v. Novo Nordisk A/S 42 USPQ2d 1001, 1997. In this case the starting material that has not been disclosed is any transgenic nematode, other than *C. elegans*, or any nematode regulatory element embraced by the claims.

It is noted that claims 96-105 are interpreted to embrace methods relating to directing expression in a *C. elegans* amphid sheath cell *in vivo* and are therefore subject to the preceding enablement rejections.

Given the lack of guidance provided by the instant specification it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 96-105 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 96, 97, 101, and 102 are incomplete as written. The claims are directed to expressing a polynucleotide or polypeptide in a *C. elegans* amphid

sheath. The steps of the methods however do not relate back to the preamble in a positive process. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 10-12, 14-29, 46, 48-50, and 53-54 are rejected under 35 U.S.C. 102(a) as being anticipated by Plenefisch et al (Molecular and Biochemical Parasitology, 2000; IDS).

The claims are directed to a transgenic nematode, the cells of which contain a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker.

Plenefisch et al teach transgenic *C. elegans* whose cells contain a transgene comprising a promoter of a gene that is the *C. elegans* homolog of an *Ascaris suum* gene encoding a secreted protein. See the abstract and throughout the document. Plenefisch teaches that the C. elegans sequences were amplified from genomic DNA approximately 1-1.2 KB upstream from the start of transcription of the lbp genes. Also, part of the lbp-1 coding sequence containing at least a secretory signal sequence was

included in one transgene. See page 226, section 2.5. The sequences of Plenefisch were subcloned in frame with a gene encoding a green fluorescent protein. The expression patterns of the secreted Ibp proteins suggest that they may be expressed and secreted through the pharyngeal glands. See pages 230-232.

Thus, the teachings of Plenefisch et al anticipate all of the instant claim limitations.

Claims 1-2, 5-7, 10-12, 14, 19, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Britton et al.

The claims are directed to a transgenic nematode, the cells of which contain a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker.

Britton et al teach transgenic *C. elegans* whose cells contain a transgene comprising a promoter of a gene, from *Haemonchus contortus* or *Ostertagia circumcincta*, encoding a secreted protein. See the abstract and throughout the document. Britton et al teaches that the *Haemonchus contortus* or *Ostertagia circumcincta* sequences were amplified from genomic DNA approximately 2-2.5 KB upstream from the start of transcription of the respective genes and subcloned into a transgene construct. Also, part of the AC-2 coding sequence containing at least a secretory signal sequence was included in one transgene. See page 172-174. The

sequences of Britton were subcloned in frame with a gene encoding a β-galactosidase. Britton also teaches that the transgenes may be extrachromosomal. See page 175.

Thus, the teachings of Britton et al anticipate all of the instant claim limitations.

Claims 1-2, 4-7, 10-18, 22, 24-25, 30-31, 46, 48-50 and 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al (BioTechniques, 1999, 26(5): 914-921: IDS).

The claims are directed to a transgenic nematode, the cells of which contain a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker.

Miller et al teach transgenic *C. elegans* whose cells contain a transgene comprising a promoter of a gene that is the *C. elegans* homolog of parasitic nematode gene encoding a secreted protein. It is noted that Miller et al does not specifically teach that the [*C. elegans*] unc-4, unc-54 or del-1 genes are homologs of parasitic nematode genes. However, it is likely that [*C. elegans*] unc-4, unc-54 or del-1 genes are homologs of parasitic nematode gene given the conservation of genes throughout species of nematodes. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products

of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. In any event, Miller et al teaches use, in a construct used to make transgenic *C. elegans*, of *C. elegans* regulatory sequences from the unc-4, unc-54 or del-1 genes that are between 1 nucleotide and 10KB upstream from the start site of transcription of the respective genes. Also, the unc-54 construct comprises the unc-54 promoter, the unc-54 nuclear localization signal, a nucleotide sequence encoding a modified fluorescent protein, a nucleotide sequence encoding β-galactosidase and the unc-54 3' untranslated region. See page 916 and also see Table 1 on page 915. The expression patterns of unc-4 and del-1 show expression in neurons. It is known the amphid sheath cells comprise neurons. Therefore, it is inherent that unc-4 or del-1 direct expression in cell of the amphid sheath absent evidence to the contrary.

Thus, the teachings of Miller et al anticipate all of the instant claim limitations.

Claims 1, 5, 6, 7, 10-12, 14, 15-18, 24-25, 30-31, 46, 48 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Signor et al (Molecular Biology of the Cell, 1999, 10: 345-360).

The claims are directed to a transgenic nematode, the cells of which contain a transgene comprising a regulatory element of a gene that encodes a nematode secretory product or homolog thereof operably linked to a DNA sequence encoding a detectable marker.

Signor et al teach transgenic *C. elegans* whose cells contain a transgene comprising a promoter of a gene that is the *C. elegans* homolog of a kinesin gene [OSM-3], particularly a kinesin II gene. Kinesins constitute a superfamily of proteins that are found in nematodes as well as other animal species. See the abstract and pages 245-246. It is noted that Miller et al does not specifically teach that the *C. elegans* OSM-3 gene is a homolog of a parasitic nematode gene. However, it is likely that the OSM-3 gene is a homolog of parasitic nematode gene given the conservation of genes throughout species of nematodes. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spade, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. In any event, Signor et al teaches use of *C. elegans* regulatory sequence from the OSM-3

gene that is 2KB upstream from the start site of transcription of the OSM-3 gene in a construct. Also, the OSM-3 construct further comprises a nucleotide sequence encoding a green fluorescent protein. See page 348. The OSM-3 promoter directs expression of the green fluorescent protein in the neurons of the amphid sheath in a transgenic *C. elegans*.

Thus, the teachings of Signor et al anticipate all of the instant claim limitations.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS, JR.
PRIMARY EXAMINER